

REMARKS**1. The Amendments and the Support Therefor**

Thirteen claims (1-13) have been canceled and five new claims (14-18) have been added, wherein:

- New claim 14 incorporates canceled claims 1-4 and 6;
- New claim 15 incorporates canceled claim 5;
- New claim 16 incorporates canceled claims 7-10 and 12;
- New claim 17 incorporates canceled claim 11;
- New claim 18 includes canceled claim 13, as well as 2-4 and 6

No new matter has been added by the amendments or new claims.

2. Rejection of Claims 1-13 under 35 USC §112(2)

These rejections have been overcome by appropriate amendments to the claims. Specifically, claims 1-13 have been canceled, and new independent claims 14 and 16 (incorporating the subject matter of claims 1 and 7 respectively) recite a composition and method of treating insect bites and stings. These claims are definite because it is no longer unclear as to what the composition and method are treating.

The rejection of claims 1, 6, 7, 12, and 13 for use of the term "non-medicinal carriers" is addressed in claims 14, 16 and 18 by defining the term as one of four potential substances (carboxymethylcellulose, glycerin, polysorbate and water). Thus, one of skill in the art would be reasonably apprised of the scope of these claims.

The rejection of claim 13 as being indefinite is overcome by canceling claim 13 and replacing it with new claim 18. New claim 18 recites a composition for use in treating insect bites by applying it topically to the affected area. Thus, new claim 18 now recites a use with an active positive step for how the use is actually practiced.

3. Rejection of Claim 13 under 35 USC §101

This rejection has been overcome by the cancellation of claim 13 and its incorporation into new claim 18. Claim 18 recites a use of a zinc oxide and sodium heparin admixture for treating insect bites and stings by "applying topically to the affected area." Since new claim 18 recites a use with the proper steps involved in the process, it is not an improper process claim under 35 USC §101.

4. Rejection of Claims 1-3 and 6 under 35 USC §102(b) in view of EP 12115A1 to Lukas

These rejections have been overcome by the appropriate amendments to the claims. New independent claim 14 incorporates rejected claims 1-3, and new claim 16 incorporates rejected claim 6, with each of new claims 14 and 16 (as well as new independent claims 16 and 18) reciting a composition for treating insect bites and stings. In contrast, *Lukas et al.* teach a composition for the treatment of viral infections (see, e.g., the title of *Lukas et al.*), not for treating insect bites. *Lukas et al.* therefore does not describe the use of the composition for treating insect bites, nor is there any matter in *Lukas et al.* that would be viewed as suggesting to one of ordinary skill in the art that the *Lukas* composition would be effective or beneficial in treating insect bites and stings. If the Office nevertheless believes *Lukas et al.* does disclose or suggest this feature, it is respectfully requested that the Office identify with particularity the location and content of the alleged disclosure or suggestion so that the Applicant may better respond.¹

The rejection also alleges that "*Lukas et al.* disclose applicant's composition comprising a therapeutically effective amount of zinc derivative ($\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$) and glycoaminoglycan (sodium heparin) admixed with carriers methylparaben and propylparaben" (Office Action, page 3). However, *Lukas et al.* teach a composition having 50 grams zinc derivative and 1.6×10^6 IU

¹ "[W]hen the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference," *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); "When relying on numerous references or a modification of prior art, it is incumbent upon the examiner to identify some suggestion to combine references or make the modification," *In re Mayne*, 41 USPQ2d 1451, 1454 (Fed. Cir. 1997); 37 CFR §1.104(c)(2).

sodium heparin (Abstract). New independent claim 14 (as well as new independent claims 16 and 18) recite a composition having 1-20 mg/g zinc oxide and 100-300 USP units/g sodium heparin (note that one IU is equal to one USP unit), as originally recited in claims 4 and 10. These amounts are not taught or suggested in *Lukas et al.*, as demonstrated by the fact that claims 4 and 10 were not rejected in view of *Lukas et al.* Further, new claim 16 recites the use of non-medicinal carriers including carboxymethylcellulose, glycerin, polysorbate and water. These carriers are also not taught or suggested in *Lukas et al.*

It is therefore submitted that the subject matter of the current claims is neither disclosed in, nor suggested by, *Lukas et al.*, and that the current claims are therefore allowable over *Lukas et al.*.

5. Rejection of Claims 1-12 under 35 USC §103(a) in view of U.S. Pub. 2002/0114847 A1 to Peshoff and U.S. Patent No. 5,899,917 to Edwards

These rejections are traversed because there is no suggestion to combine or modify *Peshoff* and *Edwards* to attain the matter of the current claims. The Office Action notes that *Peshoff* discloses a composition comprising an effective amount of a zinc derivative to promote the cleansing of wounds and to prevent the deterioration of existing wounds (Office Action, page 5). However, *Peshoff* teaches a preferred effective amount of about 5% to about 20% by weight of the composition (Paragraph 31). In contrast, new independent claim 14 (as well as new independent claims 16 and 18) recites a therapeutically effective amount of zinc oxide ranging from 0.1% (1 mg/g = .001 g/g = 0.1% by weight) to 2% (20 mg/g = .02 g/g = 2.0% by weight) by weight of the therapeutic composition. Nothing in *Peshoff* would suggest to one of skill in the art to modify the amount of zinc derivative to the significantly lower values currently claimed.

Further, the Office Action notes that *Peshoff* does not teach the use of a heparin derivative and a non-medicinal carrier as recited in the current independent claims 14, 16, and 18, but alleges that it would have been obvious to one of ordinary skill in the art to combine the modified zinc derivative taught in *Peshoff* with the use of heparin taught in *Edwards*. However, *Edwards* does not teach the use of heparin derivatives for use in treating insect bites or stings (or for any

other topical purpose), and rather teaches the use of heparin as one of many compounds useful in the prevention of restenosis (col. 15, lines 44-48) and in stent compositions (col. 26, lines 16-22). Thus, *Edwards* is not at all about treatment of bites or external wounds, but is rather directed towards a stent for use within a lumen/vessel of a human body. Nothing in *Edwards* suggests that heparin would be useful in combination with zinc derivatives for the treatment of insect bites and stings; the fields of use are nonanalogous such that one would not look to the field of stents for a solution to issues in the bite treatment field, nor would one assume that the teachings of *Edwards* would be useful in this field.

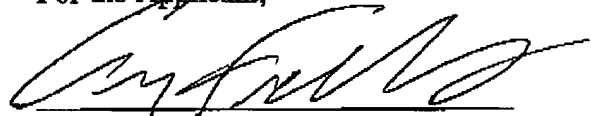
Additionally, nothing in *Edwards* suggests that heparin derivatives are beneficially used with non-medicinal carriers such as carboxymethylcellulose, glycerin, polysorbate or water for use in bite treatment. *Edwards* teaches the use of water as a compound with a high susceptibility and absorbance for microwave energy (col. 25, lines 14-19) and as a component in a liquid vehicle electrolyte with sufficient ionic strength to conduct electric current or RF energy (col. 26, lines 5-9). Thus, *Edwards* selects water owing to its electromagnetic qualities, a purpose which is not relevant to the objectives of the current claims. *Edwards* therefore does not truly and objectively teach nor suggest that water is a beneficial non-medicinal carrier for bite treatment compositions, nor does *Edwards* teach the use of other non-medicinal carriers like carboxymethylcellulose, glycerin or polysorbate. Further, *Edwards* provides no suggestion to combine such non-medicinal carriers with heparin and zinc derivatives.

In summary, there is no suggestion in the cited references to modify the therapeutically effective amount of zinc derivative taught in *Peshoff* to the dramatically lower values recited in claims 14 and 16; there is no true suggestion to combine the zinc derivative taught in *Peshoff* with the heparin taught in *Edwards*; and there is no suggestion to modify the use of water taught in *Edwards* (as a material with desirable electromagnetic qualities) to include use as a non-medicinal carrier like carboxymethylcellulose, glycerin or polysorbate. Thus, it is submitted that the current claims are allowable over *Peshoff* and *Edwards*.

6. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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